

**REMARKS**

**Status of Claims**

Upon entry of this amendment, only newly presented claim 43–61 will be pending in this application, claims 8, 10, 15, 17 and 29-42 being cancelled in this paper. In the Preliminary Amendment dated April 30, 2004, two consecutive claims were inadvertently numbered as claim 32 and as a result all claims following the first claim 32 were incorrectly numbered. The new claims are added to correct the erroneous numbering but otherwise correspond identically to the previously pending claims. No new matter is introduced.

**Claim Rejections under 35 U.S.C. §103**

The Examiner has rejected claims previous claims 8, 10, 15, 17 and 29-42 under 35 U.S.C. §103(a) as obvious over Zastrow, et al. (WO 99/38483, abstract) in view of Lapinet, et al. (U.S. 3,978,213), Tomina, et al. (U.S. 5,314,873), Peyronel, et al. (WO 92/04420, abstract), Chambers, et al. (WO 97/27835), Moller, et al. (U.S. 4,496,536), JP 09030946 and Babisch, et al. (WO 96/17605). Applicants traverse these rejections.

Claim 43 (formerly claim 8) is the only independent claim in the application. It is directed to the topical use of andrographolide and certain derivatives to improve the aesthetic appearance of skin, “wherein the improvement is selected from the group consisting of the reducing in appearance of wrinkles, the reduction in appearance of fine lines, smoothness, texture, firmness, moisture level, the size of pores, the number of pores, elasticity, firmness, resiliency, and any combinations thereof.”

The only reference cited by the Examiner which even remotely relates to the use of andrographolide compounds is JP 09030946 which, according to the Examiner, “teaches the use of extracts of Andrographis in oil-in-water preparations for skin lightening which inhibits melanin formation and tyrosinase.” The Examiner also cites WO 96/17605, presumably to establish that the extracts of Andrographis of JP 09030946 comprise andrographolide compounds. The Examiner acknowledges that the “prior art does not expressly disclose the claimed method of improving the aesthetic appearance of the skin in which the composition contains andrographolide” but nevertheless contends that “one of ordinary skill in the art would have been motivated to modify the prior art to prepare a composition for treating skin with the expectation that the composition would be effective for treating wrinkles, rejuvenating skin and

ameliorating skin dryness, chapping, aging and enhancing the quality and flexibility of the skin.” The Examiner’s position is without legal or scientific basis.

As admitted by the Examiner, the cited art does not disclose that andrographolide compounds have any utility in “the reducing in appearance of wrinkles, the reduction in appearance of fine lines, smoothness, texture, firmness, moisture level, the size of pores, the number of pores, elasticity, firmness, resiliency, and any combinations thereof” as required by claim 43. The Examiner has offered no scientific rationale in support of the contention that one skilled in the art would have an “expectation that the composition would be effective” in treating or improving these skin indications. The Examiner does not argue that tyrosinase or melanin are implicated in any of the conditions recited in claim 43 and thus it is not seen that the inhibition of tyrosinase or melanin with extracts of Andrographis, as taught by JP 09030946, would have motivated one skilled in the art, with a reasonable expectation of success, to use andrographolide compounds to treat wrinkles, etc. The Examiner’s reliance on the other cited art as teaching cosmetic use of various (non-andrographolide) ingredients cannot rectify this basic deficiency of the rejection because these other components are not recited in claim 43. The fact that non-andrographolide compounds or natural extracts have allegedly been used in compositions for treating wrinkles, etc. is irrelevant to the patentability of independent claim 43.

None of the cited art, whether taken alone or in combination, remotely suggests the use of andrographolide compounds in improving the aesthetic appearances of skin, the improvement being selected from the appearance of wrinkles or fine lines, smoothness, texture, firmness, moisture level, the size of pores, the number of pores, elasticity, firmness, or resiliency. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

Having distinguished independent claim 43 from the cited art, the claims dependent therefrom are patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of these claims in the future, should that be necessary.

#### **Double Patenting**

The Examiner has provisionally rejected claims 8, 10, 15, 17 and 29-42 over claims 29-31, 36 and 38-44 of copending application No. 11/040,534 in view of Zastrow, et al. (WO 99/38483, abstract) in view of Lapinet, et al. (U.S. 3,978,213), Tomina, et al. (U.S. 5,314,873), Peyronel, et al. (WO 92/04420, abstract), Chambers, et al. (WO 97/27835), Moller, et al. (U.S. 4,496,536), JP 09030946 and Babisch, et al. (WO 96/17605).

Applicants submit herewith a Terminal Disclaimer which disclaims the terminal part of the statutory term of any patent granted on the instant application that would extend beyond the expiration date of the full statutory term of a patent issuing from U.S. Patent Application No. 11/040,534. Entry of this Terminal Disclaimer is respectfully requested.

**CONCLUSION**

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested.

In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

Dated: March 27, 2008

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